

# Small balloon strategy associated with low pacemaker implantation rate after self-expanding transcatheter valve implantation

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**BACKGROUND:** This study aims to investigate whether small balloon aortic valvuloplasty (BAV) reduces the need for permanent pacemaker implantation (PPMI) after transcatheter aortic valve implantation (TAVI).

**METHODS:** This was a retrospective analysis using data from our local TAVI database. Small BAV was defined as a small balloon size ( $\leq 18$  mm) pre-dilatation. Normal BAV was defined as a balloon size  $>18$  mm. The primary endpoint was the incidence of new PPMI.

**RESULTS:** Of 99 consecutive TAVI patients, five patients were excluded due to pre-existing permanent pacemaker. Patients in the small BAV group ( $n=57$ ) had a significantly lower PPMI rate compared with the normal BAV group ( $n=37$ ) (3.5% vs. 18.9%,  $P=0.026$ ). Moderate or severe aortic valve regurgitation post-procedure was similar between the small BAV and normal BAV groups (5.3% vs. 8.1%,  $P=0.480$ ); likewise, the mean aortic gradient post-procedure did not differ significantly ( $11.5\pm 5.2$  mmHg vs.  $12.2\pm 7.3$  mmHg,  $1$  mmHg=0.133 kPa,  $P=0.580$ ) between the groups. Device success rates were also similar (94.7% vs. 91.8%,  $P=0.680$ ). In multivariable analysis, small BAV ( $P=0.027$ ), the ratio of prosthesis diameter to annulus diameter ( $P=0.048$ ), and mean aortic gradient by echo in the basement ( $P=0.021$ ) were independent predictors of PPMI.

**CONCLUSIONS:** The small BAV strategy is associated with a low rate of permanent pacemaker implantation after transcatheter self-expanding valve implantation in this single-center observational study.

**KEYWORDS:** Transcatheter aortic valve implantation; Balloon aortic valvuloplasty; Balloon size; Permanent pacemaker implantation

World J Emerg Med 2021;12(1):48–53  
DOI: 10.5847/wjem.j.1920-8642.2021.01.008

## INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is increasingly applied for treating patients with severe symptomatic aortic stenosis.<sup>[1-3]</sup> One of the most common complications after TAVI is the need for new permanent pacemaker implantation (PPMI), especially in patients with self-expanding prostheses.<sup>[4]</sup> New PPMI is related to a longer hospitalization duration, reduced survival, and higher rates of repeated hospitalization.<sup>[5]</sup> Thus, the reduction of PPMI incidence after TAVI is a worthwhile goal.

Multiple reports state that balloon aortic valvuloplasty (BAV) is associated with the development of conduction disorders.<sup>[6-8]</sup> However, few studies have investigated the relationship between balloon size in BAV and the rates of PPMI. We hypothesize that the small balloon size in BAV is associated with a decrease in the PPMI rate. Therefore, this study aims to investigate whether a small BAV strategy reduces the need for permanent pacemakers after TAVI with a self-expanding transcatheter valve.

## METHODS

### Study design

This was a retrospective analysis using data from our local TAVI database that included 99 consecutive high-to-prohibitive surgical risk patients with severe aortic stenosis undergoing TAVI between 2015 and 2018. Baseline demographics, procedural data, and clinical outcomes were prospectively collected, while the analysis was performed retrospectively. All patients received pre-dilation using a Z-Med balloon (NuMED, Hopkinton, New York, USA) under rapid pacing routinely. The choice of balloon size in BAV was based on the operator preference in all cases. The size of the balloon was 18–23 mm in the first 65 patients and 18 mm in the last 34 patients after noticing that PPMI occurred less after the utilization of a smaller valvuloplasty balloon. The 18-mm balloon was the smallest available balloon. Thus, patients were divided into two groups based on the balloon size of BAV: the small BAV group (balloon size=18 mm) and the normal BAV group (balloon size >18 mm). If BAV was performed for two times, the bigger balloon size was used for classification. Baseline characteristics and clinical outcomes were compared between the two groups. The primary endpoint was the incidence of new PPMI. The indications for new PPMI were unrecovered high degree or III° atrioventricular block at any time during or after TAVI or by symptomatic bradycardia after TAVI. However, asymptomatic left bundle branch block (LBBB), I° and II° atrioventricular block, was not viewed as an indication for PPMI.

### Patients and procedures

All potential TAVI candidates were assessed by a local heart team, including interventional cardiologists and cardiac surgeons. Severe aortic valve stenosis was defined by echocardiographic criteria including a mean gradient >40 mmHg (1 mmHg=0.133 kPa) or peak jet velocity >4.0 m/s and aortic valve area <0.8 cm<sup>2</sup> or aortic valve area index <0.5 cm<sup>2</sup>/m<sup>2</sup>. Baseline surgical risk was estimated using the European logistic system for cardiac operative risk evaluation (EuroSCORE) and Society of Thoracic Surgeons (STS) score. Multi-slice computed tomography (MSCT) was performed to assess aortic valve anatomy and vascular access. The transfemoral-first approach rule was preferred.

General anesthesia was generally used in our TAVI procedure. Transesophageal echocardiography (TEE) and angiography were used for procedural guidance during the index procedure. Self-expanding prostheses

were used in all patients, including two domestic self-expanding transcatheter heart valves (THVs): Venus A (Venus Medtech Inc., Hangzhou, China) and VitaFlow valve (Shanghai MicroPort CardioFlow Medtech Co., Ltd., Shanghai, China). The design of both domestic devices is similar to that of the Medtronic CoreValve (Medtronic Inc., Minneapolis, USA). An aorta angiogram and echocardiography were used to evaluate regurgitation. The implantation depth was defined as the distance from the native aortic annulus plane to the left ventricular edge of the THV by fluoroscopy.<sup>[9,10]</sup> A post-balloon dilation was performed if a more severe than moderate aortic valve regurgitation (AVR) and high transvalvular gradient existed. The post-dilation balloon size was generally 3–4 mm larger than the diameter of the narrowest part of the stent after implantation, as measured by fluoroscopy. The site-specific institutional review boards approved the protocol and consent forms. Written informed consent was obtained from all patients.

### Statistical analysis

All statistical analyses were performed using SPSS version 19.0. Continuous variables were expressed as mean±standard deviation. Categorical variables were presented as numbers and proportions (%). Comparisons between the two groups (small BAV group and normal BAV group) were performed using the Chi-square test or Fisher exact test for categorical variables, and independent *t*-test for continuous covariates. To identify independent predictors of PPMI, candidate variables for the multivariable model were required to have clinical relevance and a *P*-value <0.15 in the univariate analysis, which included all available baseline clinical, echocardiographic, electrocardiogram (ECG), and procedural data. A value of *P*<0.05 was considered significant.

## RESULTS

### Patient population

From the initial cohort of 99 patients, five had to be excluded because of a previous PPMI. Of the remaining 94 patients, small balloon pre-dilatation (=18 mm) was performed in 57 patients, regarded as the small BAV group, whereas 37 patients received balloon with pre-dilatation >18 mm, which were considered as the normal BAV group. Baseline characteristics are displayed, stratified by small BAV and normal BAV groups, as shown in Table 1. There were no significant differences between groups with respect to demographic characteristics, ECG characteristics, annulus diameter,

percentage of the bicuspid valve, and echocardiographic variables, including mean aortic gradient, aortic valve area, left ventricular end-diameter, left ventricular ejection fraction (LVEF) (Table 1).

### Procedural and clinical outcomes

Procedural characteristics are presented in Table 2. The prosthesis size was significantly larger in the normal BAV group than in the small BAV group ( $27.6\pm 1.9$  mm vs.  $25.7\pm 1.8$  mm,  $P<0.001$ ). There were no significant differences in the implantation depth, prosthesis diameter ratio to annulus diameter, or post-dilation rate between the two groups (all  $P>0.05$ ). Procedural and clinical outcomes are shown in Table 3. There were no significant differences in severe or moderate AVR, post-procedural mean aortic gradient, or post-procedural aortic valve area (all  $P>0.05$ ). Only one patient experienced severe AVR and conversion to surgery (normal BAV group) due to migration of the prosthesis, while no statistically significant difference was detected in the rate of device success ( $94.7\%$  vs.  $91.8\%$ ,  $P=0.680$ ). Notably, the proportion of patients requiring new PPMI was significantly lower in the small BAV group than in the normal BAV group ( $3.5\%$  vs.  $18.9\%$ ,  $P=0.026$ ).

### Multivariable analysis

All 94 patients completed a 30-day follow-up, and there were no new pacemaker implantations observed after discharge. The rate of PPMI in the entire population was  $9.6\%$ . The candidate variables for the univariate logistic regression analysis for predictors of PPMI are shown in Table 3. Candidate variables for the multivariable model were required to have clinical relevance and a  $P$ -value  $<0.15$  in the univariate analysis. Interestingly, the mean implantation depth was a predictor of new PPMI on univariate analysis. However, on multivariate analysis, where other parameters were selected as confounders, the mean implantation depth was not significantly different (Table 3). By multivariate analysis, predictors of PPMI included small BAV (odds ratio [OR]  $21.30$ ,  $95\%$  confidence interval [CI]  $1.41$ – $321.18$ ,  $P=0.027$ ), prosthesis diameter/annulus diameter (for each  $0.1$  increment, OR  $2.70$ ,  $95\%$  CI  $1.00$ – $7.31$ ,  $P=0.048$ ), and mean aortic gradient by echo at basement (for each  $1$  mmHg increment, OR  $-1.08$ ,  $95\%$  CI  $-1.01$  to  $-1.16$ ,  $P=0.021$ ), as shown in Table 3.

## DISCUSSION

This study's objective is to test our hypothesis that a small balloon strategy in BAV is associated with low

PPMI after TAVI. The primary results of our study were as follows: (1) the rate of new PPMI after TAVI in the whole cohort was low ( $9.6\%$ ); (2) the rate of PPMI in the small BAV group was significantly lower than that in the normal BAV group, while the hemodynamic parameter, procedure success rate, and clinical outcomes were not different between the two groups; (3) small balloon strategy and prosthesis diameter/annulus diameter were independent predictors of PPMI after TAVI.

Current evidence shows that the PPMI rate is more frequent after TAVI with a self-expanding valve than the balloon-expandable valve.<sup>[11]</sup> Regarding self-expanding prostheses, the PPMI rates were higher with the early first-generation CoreValve device ( $16.3\%$ – $37.7\%$ ),<sup>[12-14]</sup> and despite a reduction in PPMI rates with the new Evolut R, the rates remained relatively higher ( $14.7\%$ – $26.7\%$ ).<sup>[15,16]</sup> The new PPMI rate in this study was lower ( $9.6\%$ ), which was also lower than in the Chinese Venus A analysis ( $18.8\%$ ).<sup>[17]</sup> In this study, the  $18$ -mm balloon during BAV was used in  $60.6\%$  of patients. This indicates that the balloon size during BAV in our cohort was generally smaller than that in other studies.

In a previous study<sup>[13]</sup> using the CoreValve prosthesis, pre-dilatation with a smaller valvuloplasty balloon resulted in significantly lower PPMI rates. Notably, in that study, only  $1.2\%$  of patients were treated with an  $18$ -mm balloon during BAV, and most balloon sizes were  $23$ – $25$  mm. However, in this study, a balloon of  $18$ -mm diameter or no balloon valvuloplasty was performed in more patients ( $60.6\%$ ). This might partially explain the lower rate of PPMI after TAVI in the present study ( $9.6\%$ ). This was also consistent with the logistic regression analysis result: a valvuloplasty balloon of greater diameter was found to be an independent predictor of PPMI.<sup>[13]</sup> These findings support our results, stating that a small BAV strategy may be more effective in reducing the need for new PPMI after TAVI.

There are several potential explanations for the association of small balloon strategy with low PPMI after TAVI. First, a small BAV results in a small supra-annular structure orifice before the final deployment; thus, small-sized prostheses could be anchored. A prosthesis to left ventricular outflow tract diameter and left ventricular end-diastolic dimension ratio is identified as a novel predictor of PPMI.<sup>[18]</sup> Moreover, in this study, the multivariable analysis demonstrated that the prosthesis diameter/annulus diameter was a predictor of new PPMI (for every  $0.1$  increments, OR  $2.70$ ,  $95\%$  CI  $1.00$ – $7.31$ ,  $P=0.048$ ). With the small BAV strategy, the small BAV group had a significantly smaller prostheses

**Table 1.** Baseline characteristics

Parameters	Small BAV (balloon size=18 mm, n=57)	Normal BAV (balloon size >18 mm, n=37)	P-value
Age (years), mean±SD	78.5±7.3	77.2±6.1	0.38
Male, n (%)	37 (64.9)	26 (70.3)	0.66
BMI (kg/m <sup>2</sup> ), mean±SD	23.1±3.2	22.2±3.7	0.26
STS score (%), mean±SD	9.6±5.8	9.8±6.2	0.94
Logistic EuroSCORE, mean±SD	4.2±2.6	5.8±7.7	0.22
NYHA functional class, n (%)			
III	25 (43.9)	17 (45.9)	0.54
IV	7 (12.3)	7 (18.9)	0.42
Aortic annulus diameter by MSCT (mm), mean±SD	24.8±2.6	25.9±2.9	0.12
ECG characteristics, n (%)			
LBBB	3 (5.2)	4 (11.1)	0.69
RBBB	6 (10.3)	4 (11.1)	0.62
Echocardiographic characteristics			
AV mean gradient (mmHg), mean±SD	53.3±19.8	52.8±15.6	0.90
Aortic valve area (cm <sup>2</sup> ), mean±SD	0.66±0.13	0.68±0.18	0.67
LVEDD (mm), mean±SD	49.0±7.6	51.3±6.7	0.14
Bicuspid valve, n (%)	25 (43.9)	18 (48.6)	0.68
LVEF (%), mean±SD	57.5±10.3	54.6±12.4	0.22
AVR more than moderate, n (%)	22 (38.6)	14 (37.8)	0.35
MVR more than moderate, n (%)	62.4±7.8	57.7±10.7	0.06

BAV: balloon aortic valvuloplasty; BMI: body mass index; STS: Society of Thoracic Surgery; EuroSCORE: European system for cardiac operative risk evaluation; MSCT: multi-slice computed tomography; ECG: electrocardiogram; LBBB: left bundle branch block; RBBB: right bundle branch block; NYHA: New York Heart Association classification; AV: aortic valve; LVEDD: left ventricular end diastolic diameter; LVEF: left ventricular ejection fraction; AVR: aortic valve regurgitation; MVR: mitral valve regurgitation; SD: standard deviation.

**Table 2.** Procedural characteristics and clinical outcomes

Parameters	Small BAV (balloon size=18 mm, n=57)	Normal BAV (balloon size >18 mm, n=37)	P-value
Prosthesis size (mm), mean±SD	25.7±1.8	27.6±1.9	<0.001
Post-dilation, n (%)	19 (33.3)	15 (40.5)	0.520
Post-dilation balloon size (mm), mean±SD	21.0±1.6	22.1±2.7	0.140
Prosthesis (diameter/annulus diameter), mean±SD	1.04±0.09	1.05±0.08	0.670
Implantation depth (mm), mean±SD	4.2±3.1	4.9±3.7	0.330
Device success, n (%)	54 (94.7)	34 (91.8)	0.680
Mean gradient post procedure (mmHg), mean±SD	11.5±5.2	12.2±7.3	0.580
Severe or moderate AVR, n (%)	3 (5.3)	3 (8.1)	0.480
Aortic valve area post TAVI (m <sup>2</sup> )	1.8±0.4	1.8±0.3	0.720
LVEF post procedure (%), mean±SD	61.6±8.5	58.1±10.1	0.080
Permanent pacemaker implantation, n (%)	2 (3.5)	7 (18.9)	0.026
Conversion to surgery, n (%)	0	1 (2.7)	0.400
Stroke or TIA, n (%)	0	0	–
Duration of hospitalisation (days), mean±SD	12.2±6.0	12.6±6.8	0.800
30-day mortality, n (%)	0	1 (2.7)	0.400

BAV: balloon aortic valvuloplasty; LVEF: left ventricular ejection fraction; AVR: aortic valve regurgitation; TIA: transient cerebral ischemic attack; SD: standard deviation.

**Table 3.** Univariate and multivariable predictors of the implantation of permanent pacemaker after TAVI

Variables	Univariate analysis				Multivariable analysis			
	OR	Lower 95% CI	Upper 95% CI	P-value	OR	Lower 95% CI	Upper 95% CI	P-value
Age	1.01	0.91	1.11	0.910	–	–	–	–
Male	0.55	0.11	2.83	0.480	–	–	–	–
NYHA III or IV	0.99	0.92	1.07	0.830	–	–	–	–
STS score	0.95	0.80	1.11	0.510	–	–	–	–
Logistic EuroSCORE	0.81	0.54	1.23	0.330	–	–	–	–
CAD	1.70	0.40	7.23	0.480	–	–	–	–
AVA by echo base	2.90	0.04	227.77	0.630	–	–	–	–
Mean aortic gradient by echo at basement	1.04	1.00	1.07	0.060	–1.08	–1.01	–1.16	0.021
LVEF	0.97	0.92	1.03	0.320	–	–	–	–
Pre-existing LBBB	0.71	1.80	2.83	0.630	–	–	–	–
Pre-existing RBBB	1.78	0.42	7.58	0.440	–	–	–	–
Device brand	3.07	0.27	35.55	0.400	–	–	–	–
Valve size	1.24	0.87	1.77	0.240	–	–	–	–
Prosthesis diameter/annulus diameter (per 0.1 increment)	2.12	0.98	4.59	0.056	2.70	1.00	7.31	0.048
Implantation depth	1.24	1.01	1.52	0.038	1.18	0.89	1.57	0.250
Small balloon valvuloplasty	6.41	1.25	32.86	0.026	21.30	1.41	321.18	0.027
Post-dilation	1.15	0.27	4.92	0.850	–	–	–	–
Post-dilation balloon size	0.78	0.36	1.70	0.530	–	–	–	–

TAVI: transcatheter aortic valve implantation; NYHA: New York Heart Association classification; STS: Society of Thoracic Surgery; EuroSCORE: European system for cardiac operative risk evaluation; CAD: coronary artery disease; AVA: aortic valve area; LVEF: left ventricular ejection fraction; LBBB: left bundle branch block; RBBB: right bundle branch block; OR: odds ratio; CI: confidence interval.

deployment ( $27.6 \pm 1.9$  mm vs.  $25.7 \pm 1.8$  mm,  $P < 0.001$ ), thus attributing to a low rate of new PPMI. Second, a small BAV causes less damage to the conduction system than a balloon with a large diameter. Furthermore, after a small BAV, prostheses are easily expanded, exerting less force on the annular.

A small balloon size strategy may cause concerns about the incomplete expansion of prostheses. Also, it may increase the rate of AVR and aortic gradient after the procedure. Another concern regarding impaired self-expansion is the migration of prostheses due to leaflet incompetence, significant AVR, or further need for post-dilation.<sup>[19]</sup> In this study, we did not find any differences in aortic regurgitation grades and AVR rates between the two groups. Indeed, these results are in line with previously reported evidence. Grube et al<sup>[20]</sup> reported no difference in aortic regurgitation with or without balloon pre-dilation in 60 CoreValve implantations. Fiorina et al<sup>[21]</sup> found a lower incidence of moderate to severe AVR without pre-implantation BAV.

A previous study<sup>[22]</sup> identified implantation depth as a risk factor for PPMI. In our series, the mean implantation depth was a predictor of new PPMI on univariate analysis. However, on multivariate analysis, implantation depth was not an independent predictor. The reason might be that the small BAV strategy has adjusted the effect of PPMI. Notably, there were 19 cases in our series with the implantation depth  $>6$  mm, and we did not find any conduction disorder.

Interestingly, the mean aortic gradient by echo in the basement is found to be another independent predictor of new pacemaker implantation after TAVI. New PPMI may be less frequent in patients with a higher mean aortic gradient in the basement. This may be partially explained by the fact that a high aortic gradient is normally related to a small aortic valve orifice area and high calcium load; therefore, it is easy to under-expand for the device, resulting in less pressure in the landing zone. Unfortunately, the calcification load was not analyzed in this study due to the absence of data. More research is warranted. In addition, most predictive methods for PPMI are pre-existing RBBB in other studies. Interestingly, pre-existing RBBB was not a predictor in our study. In our patient cohort, pre-existing RBBB rate was 10.6%, which was lower than that reported in other studies.<sup>[23]</sup> This might be a partial reason for this.

This study had several limitations. First, the study was a retrospective analysis with a small number of patients within each group. Second, this study was a

non-randomized trial. Importantly, a selection bias was possible. Whether or not to use a small BAV was made by the TAVI team operator, who had a perception of successful valve delivery. Further studies, including many patients, are needed to ascertain small BAV strategy as a standard practice.

## CONCLUSIONS

With a small BAV strategy, a very low rate of new PPMI is achieved without increasing the amount of AVR, similar hemodynamic performance, and similar device success rate. A small BAV strategy is feasible and beneficial in our single-center experience. Further studies, including a large number of patients, are needed to ascertain small BAV strategy as a standard practice.

**Funding:** This work was supported by National Key R & D Plan (2017YFC1104202).

**Ethical approval:** The protocol was approved by the Site-specific Institutional Review Boards.

**Conflicts of interests:** The authors declare no conflicts of interest.

**Contributors:** YZ and WZP contributed equally to this work. All authors revised and approved the final version of the manuscript.

## REFERENCES

- Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet*. 2015;385(9986):2477-84.
- Kapadia SR, Leon MB, Makkar RR, Tuzcu EM, Svensson LG, Kodali S, et al. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet*. 2015;385(9986):2485-91.
- Reardon MJ, van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2017;376(14):1321-31.
- Siontis GC, Jüni P, Pilgrim T, Stortecky S, Büllsfeld L, Meier B, et al. Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVR: a meta-analysis. *J Am Coll Cardiol*. 2014;64(2):129-40.
- Nazif TM, Dizon JM, Hahn RT, Xu K, Babaliaros V, Douglas PS, et al. Predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement: the PARTNER (Placement of AoRtic TraNscathetER Valves) trial and registry. *JACC Cardiovasc Interv*. 2015;8(1):60-9.
- Banerjee K, Kandregula K, Sankaramangalam K, Anumandla A, Kumar A, Parikh P, et al. Meta-analysis of the impact of avoiding balloon pre-dilation in transcatheter aortic valve implantation. *Am J Cardiol*. 2018;122(3):477-82.

- 7 Ben-Dor I, Pichard AD, Satler LF, Goldstein SA, Syed AI, Gaglia MA Jr, et al. Complications and outcome of balloon aortic valvuloplasty in high-risk or inoperable patients. *JACC Cardiovasc Interv.* 2010;3(11):1150-6.
- 8 Kapadia SR, Goel SS, Yuksel U, Agarwal S, Pettersson G, Svensson LG, et al. Lessons learned from balloon aortic valvuloplasty experience from the pre-transcatheter aortic valve implantation era. *J Interv Cardiol.* 2010;23(5):499-508.
- 9 Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the valve academic research consortium-2 consensus document. *Eur Heart J.* 2012;33(19):2403-18.
- 10 Ali OF, Schultz C, Jabbour A, Rubens M, Mittal T, Mohiaddin R, et al. Predictors of paravalvular aortic regurgitation following self-expanding Medtronic CoreValve implantation: the role of annulus size, degree of calcification, and balloon size during pre-implantation valvuloplasty and implant depth. *Int J Cardiol.* 2015;179:539-45.
- 11 van Rosendaal PJ, Delgado V, Bax JJ. Pacemaker implantation rate after transcatheter aortic valve implantation with early and new-generation devices: a systematic review. *Eur Heart J.* 2018;39(21):2003-13.
- 12 Petronio AS, de Carlo M, Bedogni F, Marzocchi A, Klugmann S, Maisano F, et al. Safety and efficacy of the subclavian approach for transcatheter aortic valve implantation with the CoreValve revalving system. *Circ Cardiovasc Interv.* 2010;3(4):359-66.
- 13 Lange P, Greif M, Vogel A, Thaumann A, Helbig S, Schwarz F, et al. Reduction of pacemaker implantation rates after CoreValve® implantation by moderate pre-dilatation. *EuroIntervention.* 2014;9(10):1151-7.
- 14 Abdel-Wahab M, Mehilli J, Frerker C, Neumann FJ, Kurz T, Tolg R, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. *JAMA.* 2014;311(15):1503-14.
- 15 Kalra SS, Firoozi S, Yeh J, Blackman DJ, Rashid S, Davies S, et al. Initial experience of a second-generation self-expanding transcatheter aortic valve: the UK & Ireland Evolut R Implanters' Registry. *JACC Cardiovasc Interv.* 2017;10(3):276-82.
- 16 Reardon MJ, van Mieghem NM, Popma JJ, Kleiman NS, Sondergaard L, Mumtaz M, et al. Surgical or transcatheter aortic valve replacement in intermediate-risk patients. *N Engl J Med.* 2017;376(14):1321-31.
- 17 Ren KD, Pu ZX, Yu L, Gao F, Wang LH, Ng S, et al. The first two cases of transcatheter mitral valve repair with ARTO system in Asia. *World J Emerg Med.* 2020;11(1):33-6.
- 18 Nazif TM, Dizon JM, Hahn RT, Xu K, Babaliaros V, Douglas PS, et al. Predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement: the PARTNER (Placement of AoRtic TraNscathetER Valves) trial and registry. *JACC Cardiovasc Interv.* 2015;8(1):60-9.
- 19 Chan PH, Mario CD, Moat N. Transcatheter aortic valve implantation without balloon pre-dilatation: not always feasible. *Catheter Cardiovasc Interv.* 2013;82(2):328-32.
- 20 Grube E, Naber C, Abizaid A, Sousa E, Mendiz O, Lemos P, et al. Feasibility of transcatheter aortic valve implantation without balloon pre-dilatation: a pilot study. *JACC Cardiovasc Interv.* 2011;4(7):751-7.
- 21 Fiorina C, Maffeo D, Curello S, Lipartiti F, Chizzola G, D'Aloia A, et al. Direct transcatheter aortic valve implantation with self-expandable bioprosthesis: feasibility and safety. *Cardiovasc Revasc Med.* 2014;15(4):200-3.
- 22 Maeno Y, Abramowitz Y, Kawamori H, Kazuno Y, Kubo S, Takahashi N, et al. A highly predictive risk model for pacemaker implantation after TAVR. *JACC Cardiovasc Imaging.* 2017;10(10):1139-47.
- 23 Schaefer A, Neumann N, Linder M, Schofer N, Schneeberger Y, Deuschl F, et al. Outcomes with a latest generation self-expandable, intra-annular, re-sheathable transcatheter heart valve system: analysis of patients with impaired left ventricular function and determinants for pacemaker implantation. *Clin Res Cardiol.* 2018;107(10):914-23.

Received May 15, 2020

Accepted after revision November 6, 2020